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Introduction

Topical corticosteroids are mainstays of dermatologic therapy used to treat psoriasis and atopic dermatitis, among other conditions. They are a therapeutic class, typically described on a rating scale based on their potency as defined on the vasoconstrictor assay (blanching of skin upon application to a healthy subject). There can be important clinical considerations that influence the prescriber's selection of a particular topical corticosteroid product for an individual patient. Both innovator (branded) and generic topical corticosteroids are available.

Psoriasis is a common, chronic, immune-mediated inflammatory skin condition associated with disability (arthralgia, pruritus) and psychosocial distress leading to decreased quality of life.[1] In a study of 32 patients with moderate-to-severe plaque psoriasis treated with a 24-week course of adalimumab, the Psychological Well-Being Index found that untreated psoriasis was associated with as much psychological impairment to the patient's well-being as major medical diseases, such as congestive heart failure, diabetes, breast cancer, and coronary artery disease.[2] Global prevalence of psoriasis is 0 to 11.8 percent.[3] Psoriasis has recently been associated with numerous serious comorbidities, including cardiovascular disease, diabetes mellitus, depression,[4] and cancer.[5] Genetic and environmental factors likely influence psoriasis,[3] with prevalence greater among Caucasians (2.5%) than African-Americans (1.3%).[6] First-line treatment of psoriasis involves topical corticosteroids and/or vitamin D analogs, which are similarly effective.[7]

Atopic dermatitis is a chronic, recurrent, often treatment-resistant, inflammatory skin condition that occurs in children and adults.[8] Atopic dermatitis is surprisingly common: About 17 percent of United States children have atopic dermatitis, of whom about 40 percent will continue to suffer from the condition into adulthood.[9] Guidelines advocate the use of topical corticosteroids as first-line therapy for atopic dermatitis.[10,11]

The purpose of this roundtable discussion was to share general prescribing considerations, pearls and pitfalls, and observations of the use of topical corticosteroids in dermatology.

In February of 2015, four dermatology thought leaders convened for a roundtable meeting to discuss optimizing topical corticosteroid therapy. The primary objective of this meeting was to bring together a panel of experts to discuss general prescribing considerations, treatment success, clinical studies, patient preferences and empowerment, adherence, product selection, brand (innovator) products versus generics, prescribing pathways, the role of systematic patient education, and potential pearls and pitfalls.

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Critical Considerations on Optimizing Topical Corticosteroid Therapy

Firas George Hougeir, MD; Fran E. Cook-Bolden, MD; David Rodriguez, MD; Joshua M. Berlin, MD

General Prescribing Considerations

Patients today are increasingly informed "healthcare consumers" and may have obtained information about their condition and treatment options—along with some buzzwords—from the Internet. Many patients expect that all dermatologic products be cosmetically appealing, and, indeed, there is considerable research devoted to making topical products as attractive as possible to patient-consumers via delivery systems.[12] Prescribers today have numerous product choices in terms of active ingredient(s), vehicle, and formulation.

Dermatologists selecting a topical corticosteroid should consider disease severity and distribution. A study of 49 psoriasis outpatients found that 74 percent of the social anxiety and avoidance behaviors experienced by patients could be traced to disease severity, helplessness, and the lack of social support; social anxiety correlated with impaired quality of life ($p \leq 0.001$).[13] Thus, prescribers must be cognizant that severe disease likely carries with it a severe psychosocial burden. This added distress may explain why patients want to see results rapidly. In a survey of 495 psoriasis outpatients in Italy, psoriasis patients expected topical products to produce results much more rapidly than did their physicians.[14] In a multicenter study from Germany (n=1833 psoriasis patients at 213 centers), greater patient satisfaction occurred when there was an improvement in their psoriasis in the past four weeks.[15] Many patients will discontinue treatment for "lack of efficacy" when they really stop treatment because results did not occur rapidly enough, according to the roundtable participants.

Patients should be educated in terms of the treatment timeline and how it maps onto reasonably anticipated results. For instance, a physician might tell a patient to use a Class I topical corticosteroid for two weeks before expecting to see any results. Alternately, a physician may tell the patient to use the entire prescription before making a decision as to whether or not the product is working. Despite the fact that patients are better informed than ever before, many still have unrealistic notions about topical therapy. When discussing treatment duration with the patient, prescribers should bear in mind that patients may not start treatment the same day they leave the clinic—it may take days for them to get around to filling the prescription, for the staff to deal with any insurance or pharmacy issues regarding the prescription, and even longer before they actually start using the product. Patients should also be educated to use the appropriate amount of product; some patients will attempt to stretch samples from the clinic (getting less than a full dose) before purchasing a prescription.

Symptomatology must play a key role in prescribing choices. Patients suffering from pruritus, burning sensations, or flaky skin often seek immediate relief. Products that do not quickly address these symptoms may be discontinued, even if they are otherwise effective. Topical products containing menthol can be particularly helpful in relieving itching and burning.[16] Menthol activates a variety of sensory neurons known as the transient-receptor-potential (TRP) channels, by increasing their intracellular calcium and initiating calcium flux across the channels. This results in a cold response at the application site that creates the characteristic cooling sensation associated with menthol.[17] The recent discovery of the TRP-M8

gene and its companion ion channel, termed "cold receptors," elucidates this effect; menthol is a natural ligand of TRP-M8.[18] Moreover, menthol may also excite gamma-aminobutyric acid (GABA) receptors and sodium channels, producing an analgesic effect.[17]

In addition, disease components must be taken into account. For example, inflammatory dermatoses may be aggravated by products that contain even small amounts of parabens or propylene glycol. Propylene glycol may function as an emollient at very low levels, but at higher levels, it may be irritating. Geographic or seasonal factors may play a role in product selection. For example, when humidity is high, less occlusive products are preferable to very occlusive products.

Defining Treatment Success

While clinical expectations are frequently discussed in the literature and among colleagues, it is the expectation of the patient that is most important to patient satisfaction and adherence. Patients and dermatologists often think of skin conditions in very different terms. For example, a dermatologist may feel treatment success is measured by a Psoriasis Area and Severity Index (PASI) score of 75, but some patients may be very pleased with PASI 50 if the affected areas are not readily visible or can be easily concealed. In fact, patients probably regard visibility as a much more important metric than total surface area affected; a patient with only a small amount of psoriasis on the face may be far more troubled with his or her condition than a patient with much more psoriasis on the legs or trunk. Visibility can be an extremely crucial issue in warmer weather, where people wear short sleeves or short pants most of the year. Fashion-conscious patients who may sometimes choose revealing garments and like to wear the fashionable color of black may find even small amounts of psoriasis and its flaking very distressing. Thus, clinicians must be sensitive to how patients define their treatment objectives and realize that patients do not always view their cutaneous conditions the way that clinicians do and set reasonable expectations and milestones.

Goal-oriented treatment between clinician and patient (and, in some cases, the patient's family) involves clearly defined expectations, patient education, a specific treatment algorithm, regular monitoring and open discussion between clinician and patient, and prompt adjustments to treatment if the goals are not met.[19]

While patients may sometimes be able to articulate specific treatment objectives, for many of them, complete and rapid clearance is the desired outcome. In clinical practice, it is more common for dermatologists to view a course of treatment as successful before the patient thinks results are adequate. In a cross-sectional study of patients receiving treatment for plaque psoriasis, 97 patients with clear skin and 441 patients with nearly clear skin were compared. Those with clear skin were significantly more likely to report that psoriasis did not adversely impact their quality of life (relative risk 1.60, 95% confidence interval, range 1.37–1.86).[20] For that reason, clinicians should be aware that there can be significant differences between patients with clear skin and those with nearly clear skin, although from the clinician's viewpoint those two patient populations can look quite similar.

Clinical Studies

Topical corticosteroids have been the subject of many reports in the literature. When comparing clinical trials, it is important to note all aspects of the study, including not just results but also the patient populations studied (size, level of disease severity).

In a Phase 3, double-blind, randomized, vehicle-controlled parallel study of desoximetasone spray 0.25% used twice daily versus a vehicle spray (control) used on the same schedule, patients with moderate-to-severe plaque psoriasis were treated for 28 days.[21] To enter the study, patients had to have a Physician Global Assessment (PGA) score of 3 (moderate) or 4 (severe) for overall disease severity and a target lesion with an area of ≥5cm for a combined Total Lesion Severity Score (TLSS) of ≥7 and a plaque elevation of ≥3; in addition, patients at baseline had to have 13 to 17 percent body surface area affected by psoriasis. At the conclusion of the study, desoximetasone spray 0.25% patients had significant improvements in PGA, TLSS, and percentage of body surface area affected compared to the control group, with no significant safety differences between groups.[21]

Data gathered from five studies (n=2,236) of another class I topical corticosteroid, clobetasol propionate 0.05% was evaluated in a 28-day study of patients with moderate-to-severe plaque psoriasis. Patients treated with clobetasol spray showed significant improvement in percentage of body surface area affected by psoriasis and their

quality of life.[22]

Topical corticosteroids may be used as monotherapy or used in combination with another agent. For example, clobetasol spray 0.05% used concomitantly with a biologic may improve results for patients with moderate to very severe psoriasis.[23] In a study of atopic dermatitis patients, combination therapy of tacrolimus plus desoximetasone 0.25% spray was more efficacious and better tolerated than tacrolimus monotherapy.[24]

The evidence supports the use of topical corticosteroids as monotherapy or in combination for psoriasis and atopic dermatitis; these products are widely prescribed and generally well-tolerated.

Patient Preference and Patient Empowerment

The elegance of the topical product's vehicle plays a crucial role in product acceptance and, indirectly, in therapeutic success. Even an optimal product will not work if the patient discontinues it because he or she dislikes it. Dermatologists should select an effective agent and offer it in a patient-accepted vehicle. The vehicle plays two key roles: first, it can improve transdermal delivery of the active ingredient,[25] and, second, it can appeal to the patient, possibly improving patient acceptance, satisfaction, and adherence. It may be helpful to set up a "sampling station" in the clinic where a patient may test two or three different product formulations with similar efficacy to decide which vehicle appeals to them the most. This should be a dermatologist-guided decision-making process in which the goal is to present the patient with therapeutically sound choices and then solicit from the patient which feels best on the skin and is logistically easier to use. The "sampling station" empowers the patient to participate more actively in therapy, in that the patient plays a decisive role in choosing the product.

The "sampling station" can also be used to allow patients to try a small amount of product on their arm to test for irritation or allergic response. Many patients come to the clinic alarmed about certain buzzwords, such as propylene glycol or parabens, seeking products free of these "dangerous" additives. Clinicians should hear their patients out and then explain why certain ingredients might be acceptable and even useful in tiny amounts for a short duration of time or on the basis of decades of clinical experience. By and large, patients who are concerned about such things as propylene glycol have already taken the time and trouble to learn about their skin condition and its treatment, and, as a result, often respond well to clinicians who can explain their prescribing choices and why the use of such additives might be acceptable or even desirable. In other words, it is not hard to educate the "informed patient" who simply does not yet have all of the information. Of course, some patients come to the clinic with a bias against corticosteroids altogether, and clinicians should allow them to sample products while educating patients that short-term topical use of corticosteroids is different than long-term use of systemic steroids.

Many factors can determine which type of product the patient likes best: patient gender, lifestyle, the local climate, individual preferences, skin type (dry-skinned patients may prefer creams or ointments), disease location, and symptoms. Choice can be highly individualized, but, overall, many patients seem to prefer sprays and foams to ointments, which can seem old-fashioned. Sprays also can cover larger areas of the body readily and may be easier to use on scalp-related conditions and on other hair-bearing areas. While the early-generation spray products were associated with a higher isopropyl alcohol content and thus burning, the latest spray-on products are much better tolerated and may be perceived, at least by younger patients, as "less medical" than traditional creams. Foam products are popular, but can be a bit more complicated to use and take slightly more time and care to apply than a spray. The main drawback of spray products is that an overzealous spray can apply the product to unaffected areas of the skin; patients should be educated at the "sampling station" as to how to properly use the spray and to avoid spraying clear skin. Although there is no strong evidence in the literature to support this, it is intuitively believed by the authors that the more the patient subjectively likes the medicine, the more adherent to therapy that patient will be.

Adherence

The lack of adherence to dermatologic therapy regimens is particularly concerning. In a small study of dermatology outpatients, about one-third of prescriptions were never filled.[26] In a

prospective study of dermatology patients, 95 percent of those prescribed a topical product under-used it or did not use it at all.[27] In a study of atopic dermatitis patients prescribed a five-day course of topical corticosteroid medication, only 40 percent of the group could be considered adherent.[28] In a systematic review of 22 studies of topical treatments for psoriasis patients, adherence rates ranged from 55 to 100 percent, and four studies found patients used only 35 to 72 percent of the recommended dose over the duration of therapy, ranging from two to eight weeks.[29]

It is not clearly understood why patient adherence to topical therapy for cutaneous conditions is so low. In some studies, patients have reported that the products took too long to apply or that they did not care for their cosmetic appearance.[29] Some patients discontinue therapy for lack of efficacy or because they suffer side effects. Nonadherence for topical versus oral products for dermatological disease may be similar,[30] but in one open prospective study of 294 psoriasis outpatients, topical therapies had better adherence rates than other therapies; the overall mean adherence rate was 60.6±33.0 percent (range 0–169%).[31]

Poor adherence is associated with poor outcomes in dermatology.[32,33] Poor adherence may expose a patient to the risk of developing a concomitant disease, which, in turn, may place a substantial burden on the patient, the clinic, the healthcare system, and public health at large. Nonadherence is inherently wasteful of health-care resources. Furthermore, the patient who is not completely compliant may mislead the prescriber into believing the medication was ineffective or that a higher dose was warranted, resulting in inappropriate prescribing adjustments that do not benefit the patient. So significant is the issue of nonadherence in public health that the World Health Organization (WHO) has stated that adherence interventions may have a far greater impact on future global health than new medications or treatments.[34]

The Topical Treatment Optimization Program (TTOP) is a patient-focused intervention aimed at improving compliance with topical therapy among psoriasis patients.[35] Based on focus groups and expert interviews, the TTOP investigators developed an educational intervention, which provided psoriasis patients with extensive information on their disease and its treatment. A checklist format was developed to standardize sessions. Patients were guided by the prescriber to select the optimal therapy for their case, then a nurse telephoned patients on the first and third week of treatment to ask how therapy was progressing. Patients were given a question-and-answer booklet and instructed as to how to read and interpret the package inserts in medications. A clinical study on the use of TTOP among psoriasis patients is ongoing and a Topical Therapy Adherence Questionnaire (TTAQ) and Patient Preference Questionnaire (PPQ) have been developed and will be subjected to validation tests.[36]

Product Selection

Dermatologists have generally good overall knowledge about the potency and allergenicity of topical corticosteroids.[37] High-strength products that can deliver good results may be an important consideration for the short-term, since fast results can provide relief to the patient and encourage future therapeutic compliance. To optimize treatment, a high-potency Class I topical corticosteroid should be considered, to which an emollient may be added. To promote adherence, the treatment should be kept as simple as possible. In some cases, combination therapy with biologics or laser therapy may be appropriate.

Spray products offer the advantage of being easy to use and those with menthol may relieve itching, which, in turn, may encourage regular use. While clobetasol and desoximetasone are both effective topical spray products, a survey of US dermatologists found that when allergy was suspected, prescribers opted for desoximetasone.[37]

Allergenicity issues may arise owing to parabens contained in some topical products. As a general rule of thumb, the fewer the number of potentially allergic components in a product, the better. Excipients are far more likely to trigger an allergy or sensitization than the corticosteroid itself.

In rare cases, patients may have a primary allergy to the corticosteroid. If that is suspected, patch testing may be conducted to confirm corticosteroid allergy. While preemptive corticosteroid allergy testing may be arguably useful, at least in theory, most dermatologists test for such allergies only when an allergic reaction is suspected, particularly since topical corticosteroids are generally well-tolerated.

For patients with allergic reactions, it may be useful to withdraw all topical products for a short period of time and rotate to oral prednisone, perhaps supplemented with an emollient. That may provide improvement and then topical

corticosteroid therapy may continue. Of course, allergic reactions may preclude topical corticosteroid use in a very small number of patients.

In cases where an adherent patient does not make expected progress, it may be useful to consider whether the patient has allergies or sensitivities. Patch testing can assess if the patient is allergic to any excipients in the product or to the corticosteroid itself. Patients with a history of allergies are often allergic to any number of substances, such as foods, fragrances, body care products, soaps, and so on. It may be that the allergic reaction was triggered by something other than the topical corticosteroid product.

Brand (Innovator) Products versus Generics

There is no question that generic drugs have changed American healthcare. Prescribing rates for generic products have increased from 19 percent in 1984[38] to 57 percent in 2005 and 75 percent in 2009.[39] Since prescription costs are a significant component of America's national healthcare expenditures,[40] the appeal of generic products to our healthcare system is the same as their appeal to consumers, namely, they cost less. In a survey of American consumers purchasing over-the-counter medications, lower prices were the single most decisive factor for selecting a generic product over a branded product.[41] These lower prices also benefit manufacturers. The cost of developing an innovator drug from concept to molecule to market launch may cost up to $1 billion dollars,[39,42] but a generic drug may be brought to market for about $1 to $2 million.[39]

The Federal Food, Drug, and Cosmetic (FDC) Act of 1938 first made provisions for generic drugs, in that it required new drugs to demonstrate safety,[43,44] but any new drugs "generally recognized as safe" (GRAS) or identical, similar, or related to approved drugs could be cleared for market release without formal United States Food and Drug Administration (FDA) approval.[45] This opened the door to thousands of unapproved, so-called "generic medicines" that became commercially available between 1938 and 1962, either as GRAS or as "similar" to approved products. The Kefauver-Harris Drug Amendment of 1962 and later the Drug Efficacy Study Implementation (DESI) Review of 1966 then mandated clinical trials to demonstrate both safety and efficacy. More recently, the Hatch-Waxman Act of 1984 allowed the FDA to approve an abbreviated new drug application (ANDA) based on an approved version of an innovator drug (also known as the reference drug) without the necessity or expense of a clinical trial.[44,46] In just two years, by 1986, the FDA had cleared more than a thousand new generic products for market release.[47]

A generic drug must possess the same indication, the same amounts of the same active ingredient(s), and have identical strength, dosage form, and route of administration as its reference drug. Furthermore, generics must be appropriately labeled and manufactured to meet the regulations set forth by the FDA's Good Manufacturing Process.[48] According to the FDA, the generic must be bioequivalent to the reference drug. For systemic medications, pharmacokinetic parameters are used to assess bioequivalence (maximal plasma concentration and area under the plasma concentration time curve). Two small-molecule systemic products may be considered bioequivalent if 90 percent of their confidence intervals (CIs) of the geometric mean response of the two formulations falls in the range of 80 to 125 percent.[46,47] For topical agents, pharmacodynamics parameters are more useful in establishing bioequivalence. For topical corticosteroids, the McKenzie-Stoughton Vasoconstriction Assay has been recognized as the only surrogate pharmacodynamics study approved by the FDA for evaluating bioequivalence in dermatologic products. This metrics evaluates blanching, which correlates with vasoconstriction and which is, in turn, a metric for drug potency.[49]

Generic products need only be bioequivalent in terms of active ingredients; generic regulations do not define the use of excipients. For that reason, a generic product may have an entirely different vehicle than its reference drug. For topical medications, where vehicle may play a crucial role in patient acceptance and even adherence, this is no trivial matter. Since excipients in topical products may cause complications, such as irritation, allergic reaction, or even variations in product efficacy,[50] dermatologists prescribing a multisource product should know which exact product the patient gets.

Patients may accept generic equivalent medications with the misunderstanding that they are getting "exactly the same product" as the brand. For instance, a patient may have a prescription for an innovator topical product without propylene glycol, only to be surprised that the "equivalent" generic product contains a

high amount of propylene glycol. For these reasons, patients should be educated as to what constitutes a generic and why, in some cases, a brand may be preferred over a generic or vice versa.

Prescribing Pathways

Prescribers have always had to be aware of which products were covered by a particular patient's insurance, but recent changes in healthcare reimbursement have made this more complicated. The Affordable Care Act ("Obamacare") is in the process of transforming healthcare reimbursement, but, at the moment, many of its regulations are incompletely enforced, some are not yet fully understood (such as tying "patient satisfaction" metrics to reimbursement),[51] and there have been and are continuing to be legal challenges, including a Supreme Court case.[52] On the one hand, millions of previously uninsured individuals now have healthcare insurance and it stands to reason that some of them might seek treatment for chronic skin conditions; on the other hand, many of these so-called Obamacare policies have such high deductibles that dermatologic treatment and prescriptions still remain cost prohibitive. As such, prescribers must be aware of all factors that influence whether or not the patient can afford to purchase the prescription.

The prescribing pathways for topical corticosteroids are not always as straightforward as one might think. If the prescriber writes a prescription using the generic name of a multisource product, then the pharmacy dispenses the generic. If the prescriber writes the prescription using the brand name of a patented product, then any number of stakeholders may have a say as to what is actually dispensed. The patient, the patient's insurance company, and the pharmacist may all be able to influence what the patient gets. If a brand is prescribed, there is the possibility that the pharmacy does not carry the brand or that the brand is unavailable—in such cases, a generic may be substituted. The pharmacist may have the branded product, but, in consultation with the patient, determine that the brand is too costly and opt for the less expensive generic. In some cases, the pharmacy has the branded product, which the patient wants to buy, but the insurance may require prior authorization or not cover that brand at all, and in such cases, a generic is dispensed instead. While patients may be able to influence the choice of generic versus brand product, patients may be making the decision based on the erroneous notion that generics and innovator drugs are exactly the same. Even highly informed patients may misunderstand the concept of "bioequivalence" as set forth by the FDA.

Furthermore, the American healthcare system is heavily biased toward generics. Pharmacy benefit management companies often encourage generics outright, offering discounts or rebates for their use to their pharmacy networks.[53] Health Management Organizations (HMOs) may require the use of generics in some situations or may impose higher co-payments for patients who want branded innovator drugs instead of generics. Fourteen states in the United States have made it a law that pharmacists must substitute generics when available, unless the physician specifies "brand only" in the prescription.[54] And sheer economics makes most generics appealing to cost-conscious consumers.

Since pharmacies do not report back to the clinic as to which exact products are dispensed, it is not unusual for the prescriber to not know which product the patient is using and whether or not that patient might be exposed to potentially irritating excipients. The problem can be compounded if the prescription is refilled and a different generic is dispensed. Another potentially confusing scenario occurs when the innovator product is dispensed initially, but the refill is a generic—patients may be alarmed and report that their prescription was changed or that the pharmacy made a mistake.

This same situation can occur when a patient samples an innovator product at the clinic, but is dispensed a generic. They notice immediately that the product they just purchased is different. And if the spray at the clinic did not burn her skin, but the generic has a high isopropyl alcohol content and does burn, the patient may be concerned, complain to the clinic or pharmacy, or simply discontinue treatment. The patient may feel misled, which can damage the trust between patient and physician, even if the prescriber can explain the situation to the patient.

There are workable if not ideal solutions to prescribing multisource products. A dermatologist may work with local pharmacies and ask them to call the clinic if a generic is substituted for an innovator product. This creates a burden for the clinic (extra time to field phone calls, document changes, and so on), but it can give prescribers greater control, which, in turn, may result in better care for patients. Prescribers should avoid creating any apparent animosity between themselves and pharmacies

for the sake of their patients. Prescribers may wish to counsel patients that if the pharmacy charges a very high rate for a particular prescription that they should refuse it and call the clinic, so that the dermatology clinic can intervene. Rather than "attack" the pharmacy, the dermatologist can simply explain that if a very high price is charged, it may be that the pharmacist is not "processing the prescription" correctly and the clinic can assist so that the patient is not charged the high amount.

This is not to disparage the use of generics altogether. Authorized generic versions with the exact same agents and excipients are not problematic, and there will be cases where generic products are serviceable and acceptable. Some patients are outspoken in their preference for generics. Patients who are prescribed branded products may complain that the dermatologist is forcing them to buy expensive products when cheaper generics are available. In the event that the innovator drug is clinically preferable to the generics, the physician should educate the patient as to why that particular choice was made. For example, the prescriber may explain that the brand-name drug uses a different carrier vehicle, which will penetrate the skin better and lead to faster results.

Patient confidence in generic medications is increasing,[55] and a study of European patients who had medications switched from innovator to generic drug did not express particular concern over the substitution.[56] However, in a mixed-methods survey of 42 European patients, about a quarter of them (24%) said they preferred the innovator drug to the generic.[57] Pharmacists may be even more convinced about generic products. In a survey, 98 percent said that generics were of similar quality to the innovator product, but nine percent thought that generics were not manufactured at the same high standards as the innovator brand. Just seven percent of pharmacists reported that they would prefer to dispense innovator drugs rather than generics to their patients, although 89 percent said that they had received patient complaints about generic products.[58]

Aligning with a specialty pharmacy to assure that patients get the brands (or generics) exactly as they are prescribed can be a useful strategy for a dermatology practice to assure "seamless access," that is, that the patient gets exactly what the dermatologist prescribed. Specialty pharmacies can present their own challenges if various branded products each recommend a different specialty pharmacy. It may be useful to develop a chart for use in the clinic showing frequently prescribed products and the specialty pharmacies in the area that carry them. More and more, specialty pharmacies with a commitment to dermatology may manage many, if not all, commonly prescribed brand-name products. Patients who are particularly loyal to their own pharmacy should be counseled about how important it is to get the right product and the role of the specialty pharmacy to preserve brand access. In some cases, the use of a specialty pharmacy may delay the dispensing of a prescription (for instance, if the pharmacy has to get approval from the insurance company), but such delays can happen with a chain pharmacy as well. In these cases, dermatologists can provide the patient with extra samples to bridge the gap until the prescription is approved.

Evaluating Products

As mentioned earlier, there can be a major "disconnect" between what dermatologists perceive as therapeutic success and what patients think. Psoriasis that a dermatologist may consider mild and thus not particularly troublesome may be extremely disturbing to the patient. The bimodal nature of conditions like psoriasis with flares and remission can cause patients tremendous distress, since they may misinterpret a flare as a sign that previous treatment was unsuccessful. Thus, dermatologists should be cautious about expressing their satisfaction with "treatment success" when the patient may still be quite troubled with the disease.

Topical corticosteroids are intended for short-term use. If a highly potent Class I topical corticosteroid is prescribed, the patient should come back to the clinic in about two weeks for an assessment. At this check-up, the dermatologist should confirm that the patient has filled the prescription, what prescription he got (brand or generic), and that the patient is using the product appropriately. It is the observation of the authors that some patients do not fill their prescriptions, but try to stretch the samples they get from the clinic to treat themselves for two weeks—with the result that they used far less than the recommended dose and did not achieve the desired results. Therefore, before determining that a course of treatment has been less than efficacious, the dermatologist should confirm that the appropriate product was used at the right dose for the right length of time. In other words, is the poor response the result of an ineffective agent or suboptimal adherence?

The dermatologist should also confirm that the patient is not experiencing side effects, irritation, or an allergic response. If the product was properly used, after two weeks there should be some obvious therapeutic results, even if the patient feels there is still a long way to go. Once the patient begins to respond to treatment, it may be useful to add vitamin D analogs to enhance treatment. Other adjunctive therapy may be considered, such as laser therapy or a biologic. Patients should also be asked about their stress levels, as stress can exacerbate cutaneous conditions. For some patients, it may be appropriate to ask them to continue using it only on weekdays with emollients only used on weekends.

The Role of Systematic Patient Education

An overarching theme of the roundtable meeting was the fundamental importance of open communication and patient education. Patients need to understand the nature of their skin condition, treatment options, therapeutic goals, and hold reasonable expectations for recovery. Today's patients often arrive at the clinic better informed and more opinionated than patients of the past, but that does not mean their understanding of their condition and its treatment is accurate, thorough, or balanced. Dermatologists must develop a systematic approach to patient education that includes information about the disease, treatment options, specific treatment algorithms, expectations about adherence, therapeutic objectives, potential side effects, and duration of therapy. One way to improve patient education is to approach it systematically with a checklist or other guided system to assure that no points are ever inadvertently omitted or overlooked. Standardizing education in a simple, straightforward system assures that patients get the information they need, even in the hectic environment of the busy dermatology clinic.

It can be useful to tell patients from the outset that they have a chronic and incurable skin condition and that they will likely have to treat it for the rest of their lives. They should be educated about the expected bimodal course of the disease, which typically cycles through flares and remissions. Patients may experience a loss of control or disappointment with flares, but flares must be viewed as the normal and expected pattern of the disease. The clinician should work with the patient to help identify potential triggers for flares, if possible. Patients should be reassured that even if they "do everything right," they may still experience flares. Since flares can exacerbate a patient's sense of helplessness and lead to reduced quality of life, it is important to address this topic as clearly as possible.

Clinicians should also empower patients with the knowledge that their condition can be managed and that there are many safe, effective products that can help control the disease and allow the patient to enjoy his or her life. Treatment fatigue can occur with any lifelong condition, and patients should be encouraged to persist in treatment to achieve optimal results. Patients should also be advised that numerous treatment options exist and since there is no "one size fits all" option, there may be some trial-and-error in the course of their treatment.

From questions collected by the National Psoriasis Foundation via a webcast on topical therapy options, it was found that 30 percent of psoriasis patients had questions about treatment side effects (predominantly with respect to topical corticosteroids), 16 percent had questions as to how to use products properly, and 11 percent asked about product efficacy.[59] Thus, patient education should address safety, efficacy, and possible side effects.

Potential Pearls and Pitfalls

Despite the wealth of safe and effective options for treating many dermatologic conditions, the dermatologist today can still encounter many pitfalls, many of which can be managed well.

- The patient may arrive at the dermatologist only after "all else fails," meaning the patient has been to his primary care physician and possibly several other physicians trying to get relief. Such patients can be angry, frustrated, or have the incorrect notion that their condition simply cannot be treated. It is important to take a patient history and find out how the patient has managed his condition previously. Dermatologists should hear out their patients to lay the groundwork for sound patient education in the future.
- Some patients may have self-diagnosed their skin condition and/or taken medication(s) prescribed to another person with the same or at least a similar condition. Some patients will take medications prescribed to another person without a clear idea as to what they are taking and why. In the patient history, the patient should be encouraged to disclose all

medications that they have taken and the results.
- Patients may also arrive at the clinic with allergic responses or irritations that are not necessarily the result of dermatologic medications. Patients should be asked specifically about over-the-counter medications they take as well as vitamins, supplements, essential oils, and so on. Patients with allergies are often allergic to numerous substances.
- Refills for a Class I topical corticosteroid should not be offered except in very specific situations (such as a patient who is known to use good judgment and who for a valid reason cannot make time for frequent check-ups at the clinic). For new patients or those not well-known to the prescribing dermatologist, refills should be avoided.
- Patients should be encouraged to sample different products to pick the one they like best, but the process should be guided by the dermatologist such that only appropriate products are offered. Samples offer the opportunity for the clinic to show how the product is to be used properly; do not assume that the patient knows not to use the product properly. For foams, show the patient how to shake and hold the dispenser. For spray products, make sure the patient is aware that the medicine should not be sprayed on unaffected areas of the skin.
- When treating pediatric patients, including teenagers, educational efforts should include guidance to the parents or guardians. Parental figures can be very important to assure treatment adherence.
- Dermatologists should make efforts to develop relationships with the local sales representatives from the various drug companies of the products they prescribe. These sales representatives can provide invaluable information on their products and may have patient educational materials or even be helpful to those patients who require indigent care.
- Avoid haphazard or as-needed patient educational efforts and opt instead for systematic approaches, using a checklist or some sort of standardized script. This will assure that all patients receive the same messages. Educational efforts may be effectively delegated to other clinicians or personnel, if need be.
- Recognize that adherence is a problem for all chronic conditions and that treatment fatigue is very common for patients with skin conditions. Encourage patients to persist in treatment. When possible, try to determine underlying reasons for nonadherence.
- Work with local pharmacies, in particular specialty pharmacies, to be sure that the prescriber retains control of what is dispensed to the patient. As much as possible, ask pharmacies to contact the clinic if they dispense a product other than the exact one prescribed. Discuss prescriptions, drug prices, insurance coverage, copays, prior authorizations, formularies, pharmacies, and dispensing practices openly with patients. Many patients are not clear about how the system works. If the dermatologist wants the patient to use an innovator product over a generic product, that should be explained to the patient, since he or she may be able to influence the pharmacy seeking to provide a generic substitution. Pricing should be discussed with highly cost-sensitive patients who may have to pay for their own prescriptions.
- A strongly opinionated patient is not necessarily the most educated patient. Many patients arrive at the clinic with bits and pieces of information. Leverage their questions and ideas into educational opportunities, providing them a more balanced view of their therapeutic options.
- Manage your patients' expectations. Even highly educated, well-informed patients can have unrealistic ideas about therapeutic success and treatment duration. Patients should know that their medication did not "fail" because it did not clear their skin in two days.

Conclusion

Patients with atopic dermatitis or psoriasis are often extremely distressed by their condition, at risk for potential comorbidities, and may arrive at the dermatology clinic frustrated by not having found adequate treatment for their condition from other practices. For such patients, the use of a Class I topical corticosteroid can be an excellent first-line therapy for the first two weeks because it will likely produce visible results that encourage the patient to continue therapy. Patients should be educated about treatment adherence (which is low in dermatology), the bimodal nature of their condition (characterized by sometimes unpredictable flares and remission), and understand that they have chronic and incurable conditions, which can be managed. Prescribers should select the optimal

product for the patient, which may be a topical corticosteroid monotherapy or a topical corticosteroid in combination with a biologic or laser therapy. Allergenicity should be considered; when it occurs, it more likely owes to the excipients than the primary corticosteroid. For this reason, prescribers should be mindful that multisource products may be available as generics, which do not necessarily have the same excipients as the innovator product. An authorized generic has the same active ingredient and exactly the same excipients, but other generic "equivalents" will have the same active ingredient but may have different excipients. Prescribers concerned about the use of generics may wish to establish relationships with local specialty pharmacies for greater control of dispensed drugs. A key element in successful therapy remains patient education, which should be done in a systematized way to assure that no main points are ever overlooked or omitted.

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